IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK & CO., INC. Plaintiff and Counterclaim Defendant, v. RANBAXY INC., AND RANBAXY LABORATORIES LIMITED Defendants and Counterclaim Plaintiffs.	)	C.A. No. 07-229 (GMS)

MERCK'S OPENING CLAIM CONSTRUCTION BRIEF

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

Plaintiff Merck & Co. ("Merck") provides this brief on the claim construction issues identified by the parties for the patent-in-suit, U.S. Patent No. 5,147,868 ("the '868 patent").

STATEMENT OF BACKGROUND FACTS

The invention of the '868 patent relates to the discovery of an entirely new class of compounds, including a compound called cilastatin. The discovery of those compounds resulted in a new, potent antibiotic product sold by Merck under the name Primaxin®. Primaxin® is a combination of (a) cilastatin and (b) imipenem, an antibiotic in the thienamycin class.

A. Development of the '868 patent invention and Merck's Primaxin® Product

Prior to the '868 patent invention, Merck had discovered a new class of antibiotics called the thienamycin class of antibiotics, including imipenem. Imipenem alone acted as a powerful antibiotic when used with bacteria in the laboratory. However, imipenem was rapidly metabolized in humans, and therefore was ineffective as a practical matter as an antibiotic in humans. Merck determined that an enzyme in the human kidney--dipeptidase--was responsible for the metabolism of imipenem. Merck also determined that, by inhibiting that enzyme, imipenem could be successfully administered to humans.

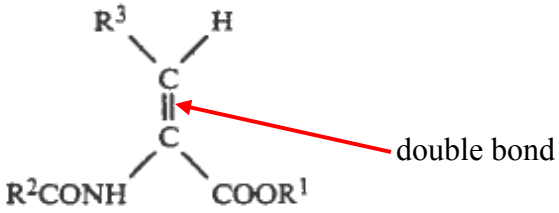
Merck discovered an entirely new class of compounds, including compounds that were more powerful in inhibiting the enzyme than existing compounds. Those novel enzyme inhibitors are claimed in the '868 patent. Significantly, one of those novel inhibitors, cilastatin, made Merck's Primaxin® product a commercial reality and gave doctors and patients an important new option for treating difficult infections. Indeed, cilastatin is critical to Primaxin®,

as without it, the imipenem in the product would be metabolized by the dipeptidase enzyme and be rendered ineffective.

Primaxin® is not available in drugstores for a patient to take orally at home, because it must be administered intramuscularly or intravenously, such as in a hospital setting. Merck typically sells Primaxin® to hospitals for use with infections that less-potent oral antibiotics cannot effectively treat.

B. The Compounds of the Patent-in-Suit

As noted, the '868 patent is directed to the invention of novel dipeptidase enzyme inhibitors, including cilastatin and other related compounds. Those compounds belong to a genus or group having common features, including at least four requirements. First the molecule must include the following structure:



(A1-21[1] at A19-20 ('868 Patent, col. 38, lns. 9-17 (claim 1); col. 39, lns. 19-26 (claim 9))). In the above figure, a double bond connects the two carbon (C) atoms at the core of the molecule. That double bond appears in cilastatin, as well as all the other compounds in the genus.

The second requirement is that the group on the lower right--the $COOR^1$ group--must have for R^1 a hydrogen, a cation or a hydrocarbon. (A1-21 at A19-20 ('868 Patent, col. 38, lns. 18-19 (claim 1); col. 39, lns. 29-31 (claim 9))).

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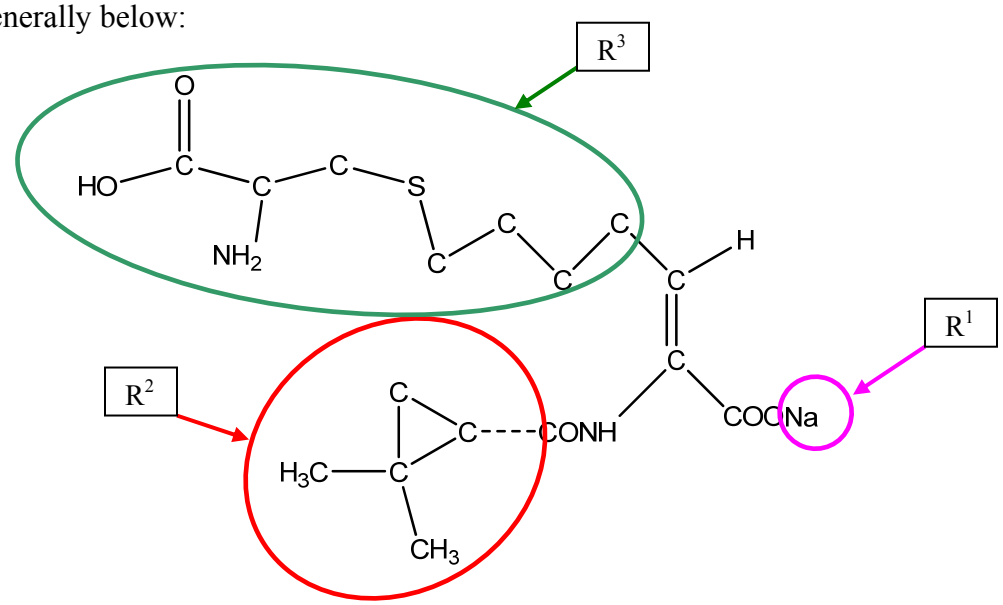
1 All citations to A numbers ("A___") refer to the Joint Appendix of Intrinsic and Extrinsic Evidence.

The third requirement is that R^2 must be a type of hydrocarbon called an alkyl. (A1-21 at A19-20 ('868 Patent, col. 38, lns 20-42 (claim 1); col. 39, lns. 27-28 (claim 9))). That requires a main backbone of carbon atoms connected together without any double bonds, but with only single bonds. For R^2, the alkyl can be either cyclic, *i.e.*, having some or all of the carbon atoms form a ring, or R^2 can be acyclic, where no rings are formed. R^2 can also have other groups attached to the carbons on its main backbone.

The fourth requirement of the genus is that R^3 must also be an alkyl, and that the alkyl have on its backbone at least two, but no more than 15, carbon atoms. R^3 can have certain groups attached to it as specified in the claim. (A1-21 at A19-20 ('868 Patent, col. 38, lns. 43-66 (claim 1); col. 39, lns. 32-36 (claim 9))).

The specific compound cilastatin is a member of that genus. It has the structure shown generally below:

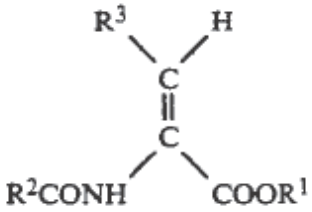


Cilastatin's R^2 group is shown in the red circle above. It includes a cyclic ring cyclopropyl (the triangle having 3 carbon atoms). The ring has two alkyls--CH_3--attached to the

cyclopropyl ring.[2] Cilastatin's R^3 group is shown in the green circle above. The group has a backbone that is a four carbon chain. The four-carbon backbone has attached to its last carbon a sulfur atom ("S") that is part of a "thio" group called 2-amino-2-carboxyethylthio. For its R^1 group, cilastatin includes the sodium ("Na") cation, circled in purple above.

C. The '868 Patent Claims

The '868 patent includes twenty-four claims, with claims 1 and 9 being the only independent claims. Claims 1 and 9 each begin with the phrase: "A compound of the formula…" Both claims then show the following formula:



Claims 1 and 9 each define the groups R^1, R^2, and R^3 in different terms. The remaining claims all depend from either claim 1 or claim 9.[3]

Claims 19 and 20 are more specifically directed to cilastatin. Claim 19, which depends from claim 9, recites: "The compound of claim 9 which is 7-(L-2-amino-2-carboxyethylthio)-2-(2,2-dimethylcyclopropanecarboxamido)-2-heptenoic acid." (A1-21 at A20 ('868 Patent, col. 40, lns. 21-23)). Claim 20 is specifically directed to salt forms of the compound of claim 19, including the sodium salt form. (A1-21 at A20 ('868 Patent, col. 40, lns. 24-25)). Cilastatin comprises a sodium salt form of the compound of claim 19.

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2 The drawing does not depict every hydrogen atom in the compound. Each carbon atom has four bonds. Whenever a carbon atom in the drawing shows less than four bonds, the additional bonds not shown are bonds to hydrogen atoms.

3 Claims 1-23 are directed to compounds, and dependent claim 24 recites a method of using the compound of claim 1 to inhibit the dipeptidase enzyme.

D. Ranbaxy's Stated Intention to Sell a Cilastatin-Containing Product

This lawsuit arose as a result of Ranbaxy's stated intention to sell a cilastatin-containing product. Specifically, Ranbaxy advised Merck that it intended to sell a generic version of Merck's Primaxin® product, which, like Primaxin®, would contain both the antibiotic imipenem and the enzyme inhibitor cilastatin. Ranbaxy also filed an Abbreviated New Drug Application ("ANDA") with the FDA seeking approval to sell its generic version of Primaxin®.

Ranbaxy seeks to sell a composition containing cilastatin in spite of the '868 patent, which discloses and claims cilastatin and which remains in force until September 2009. Accordingly, Merck filed this lawsuit. Merck asserts that Ranbaxy's ANDA product will infringe claims 1, 2, 9, 19, 20, 22, 23 and 24 of the '868 patent.

ROAD MAP TO THE PARTIES' CLAIM CONSTRUCTION DISPUTES

While the parties' Joint Claim Construction Chart points to many specific claim terms, there are six main issues that encompass all of the claim construction disputes. Accordingly, Merck will organize its brief into six sections to deal with each of these issues.

The six issues, as well as the subissues they relate to, are explained in this roadmap section. The argument section elaborates on and provides support for Merck's positions.

1. **The term "A compound" in claims 1 and 9**: The parties dispute the meaning of the term "A compound" recited in independents claims 1 and 9. The issue is whether the term "A compound" encompasses the claimed compounds when used in combination with thienamycin-class antibiotics, or whether the term "A compound" excludes such uses.

Merck contends that the term "A compound" refers to the recited compounds *per se* and that it makes no difference whether one combines them with other products or not. Ranbaxy contends that because the combination of the inhibitor compounds with thienamycin-

class antibiotics is the subject of another Merck patent, and not part of the invention of the '868 patent, the '868 patent claims cannot reach the use of the '868 patent's claimed compounds in combination with thienamycin-class antibiotics. However, the law is clear that a composition of matter patent--one claiming a new chemical compound--is infringed by any use of that compound, even if that compound is used in combination with other compounds. Indeed, even where another patent exists on a combination using that compound, that does not affect the scope of the compound patent. As long as a claim reads on part of a device or on at least one element of a combination, that is enough for infringement.

2. **The term "acid" in claim 19:** The parties dispute the meaning of the term "7-(L-2-amino-2-carboxyethylthio)-2-(2,2-dimethylcyclo-propanecarboxamido)-2-heptenoic acid" in claim 19, in particular its use of the word "acid." The parties dispute whether the word "acid" in that compound embraces acids in all of their forms—free acids, ester and salt forms—or whether it is limited to the free acid form.

Merck contends that the '868 patent uses the word "acid" to refer to compounds in each of the above three forms. Ranbaxy, however, contends that the term "acid" should always mean "free acid" whenever it is used in the '868 patent. The Federal Circuit has held that the word "acid" should be broadly construed to include salt forms of the acid, where the context of the usage of the word "acid" confirms a broad use of the word.

The '868 patent specification consistently uses the word "acid" in its broad sense to include all three forms: free acid, ester, and salt forms. For example, with respect to the acid recited in claim 19, the '868 patent specification uses the word "acid" to include the salt form of the claimed acid, stating in Example 19A "***Sodium*** Z-7-(L-amino-2-Carboxethylthio)-2-(2,2-dimethylcyclopropane carboxamido)-2-heptenoic ***acid***." (A1-21 at A17 ('868 Patent, col. 34,

lns. 11-13)) (emphasis added).[4] Plainly, the named compound in Example 19A is the sodium salt form, but the '868 patent specification still refers to it as an "acid." The '868 patent consistently uses the word "acid" in this broad sense of including the free acid, ester and salt forms.

3. **"Pharmaceutically acceptable cation" and the group R^1 definitions in claims 1 and 9.** The parties dispute whether the term "pharmaceutically acceptable cation" in claims 1 and 9 permits only "cations" that are "pharmaceutically acceptable."

Merck contends that based on the plain claim language, the term allows only "cations" that are "pharmaceutically acceptable." Ranbaxy, however, contends that the "cation" can be "***any*** cation useful in the salt form of the claimed pharmaceutical compound." (D.I. 37, Ex. A, Revised Joint Claim Construction Chart ("Joint Claim Construction Chart") at 3). Ranbaxy's construction cannot be correct, as it impermissibly reads out an express limitation of the claim term—namely, that the "cation" be "pharmaceutically acceptable."

In addition, Ranbaxy contends that the Court should construe the definition of group R^1 recited in claims 1 and 9, both of which utilize the phrase "pharmaceutically acceptable cation." In particular, claim 1 defines the group R^1 as follows: "R^1 is hydrogen or a ***pharmaceutically acceptable cation***." (A1-21 at A19 ('868 Patent, col. 38, lns. 18-19)). Similarly, claim 9 defines the group R^1 as follows: "R^1 is hydrogen, loweralkyl of 1-6 carbon atoms, dialkylaminoalkyl, or a ***pharmaceutically acceptable cation***." (A1-21 at A20 ('868 Patent, col. 39, lns. 29-31)).

Merck submits that the overall definitions of group R^1 in claims 1 and 9 require no further construction once the term "pharmaceutically acceptable cation" is construed.

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4 Unless otherwise noted, all emphasis herein has been added.

Significantly, Ranbaxy has pointed to no other portion of the definitions of R^1 that is disputed or in need of construction. Yet Ranbaxy contends that the claims' express definitions of group R^1 should be re-worded and proposes its own constructions. In so doing, Ranbaxy adds language found nowhere in the claims in its attempt to construe a claim term defined explicitly in the claim.

4. **Meaning of various composite chemical groups in claim 1 using the term "alkyl" such as "trialkylammonium."** The parties dispute the construction of nine composite terms for chemical groups specified for the R^3 group in claim 1, all which incorporate the term "alkyl" as part of a well-known chemical group, such as "tri***alkyl***ammonium."

Ranbaxy contends that each of the nine composite terms should be construed such that the term "alkyl" in each composite term means "a linear, branched, or cyclic alkyl group without limitation as to number of carbon atoms." (Joint Claim Chart at 8). Ranbaxy's proposal would construe "alkyl" without regard to the context of the chemical group as a whole. Merck contends that "alkyl" in each chemical group should be understood and defined in the context of the composite chemical group as a whole. Notably, in that context, the alkyl groups cannot contain an unlimited number of carbon atoms. To persons of ordinary skill, these composite chemical terms call to mind well-understood classes of compounds and do not refer to unrealistic compounds with an unlimited number of carbon atoms. Ranbaxy's proposal should therefore be rejected.

5. **The definitions of groups X and Y in claim 1, the definition of group R^2 in claim 22, the structural formula depicted in claims 1, 9, and the term "2,2-dimethylcyclopropyl" in claims 2, 9.** The parties dispute whether the following claim terms require any construction: (a) the definitions of groups "X" and "Y" in claim 1, (b) the definition

of group R^2 in claim 22, (c) the structural formula depicted in claims 1 and 9, and (d) the term "2,2-dimethylcyclopropyl" in claims 2 and 9.

Merck contends that none of these claim terms require any construction. Groups "X" and "Y" are expressly defined in claim 1, and there is no dispute over the meaning of any of the terms used in those definitions. The same is true of the definition of R^2, which is expressly defined in claim 22 using undisputed terms. With respect to the structural formula depicted in claims 1 and 9, there is no dispute as to what the formula itself depicts. The term "2,2-dimethylcyclopropyl" in claims 2 and 9 also needs no construction. Ranbaxy nevertheless contends that all these terms should be redefined in a manner that is unnecessary in view of the clear undisputed language in the claims.

6. **The term "said one to fifteen carbon alkyl" in claim 1.** The parties dispute the construction of the term "said one to fifteen carbon alkyl" in claim 1. Specifically, Merck contends that the word "one" in that term is a typographical error that this Court may and should correct to read "two." Ranbaxy disagrees with the proposed correction.

Claim 1 defines the group R^3 as follows, using the term "said one to fifteen carbon alkyl":

> R^3 is unsubstituted or substituted ***two to fifteen carbon alkyl*** wherein said substituent is halogen, and wherein a non-terminal methylene can be replaced by oxygen, sulfur or SO_2 and wherein the terminal carbon of said alkyl can be substituted by a moiety selected from the group consisting of [list of moieties] . . . with the proviso that no more than six hydrogens of ***said one to fifteen carbon alkyl*** can be substituted by halogen . . . ."

(A1-21 at A19 ('868 Patent, col. 38, lns. 42-61)). The phrase "***said*** one to fifteen carbon alkyl" begins with the term of art "said," meaning that it refers to a claim element identified earlier in

the claim. However, no prior claim element recites a "one to fifteen carbon alkyl." Thus, the phrase contains a typographical error apparent from the face of the patent claim itself.

Under well-established precedent, a court may correct an error in a patent claim where (1) the correction is not subject to reasonable debate based on consideration of the claim language and the specification, and (2) the prosecution history does not suggest a different interpretation of the claims. As explained in detail below, it is clear from the claim language, and explicitly confirmed in the prosecution history, that claim 1 should be corrected to read "said ***two*** to fifteen carbon alkyl."

ARGUMENT

I. THE TERM "A COMPOUND" IN CLAIMS 1 AND 9

Claims 1 and 9 both use the phrase "A compound" in their preamble. Merck proposes that the term "A compound" in claims 1 and 9 should be construed according to its clear and ordinary meaning to mean "a substance composed of atoms or ions of two or more elements in chemical combination."[5] (Joint Claim Chart at 1). Ranbaxy, on the other hand, seeks to define the term to "exclude[] a combination product containing the compound and a thienamycin-type compound." (Id.) Ranbaxy asserts that the combination product is not part of the '868 patent's invention and that the use of the claimed compounds in that product is not covered by the '868 patent claims. Ranbaxy's argument misses the point and should be rejected.

It is black letter law that "if a claim reads merely on part of an accused device, that is enough for infringement." *SunTiger, Inc. v. Scientific Research Funding Group*, 189 F.3d 1327, 1336 (Fed. Cir. 1999). Indeed, the Federal Circuit has "never required that a claim read on the entirety of an accused device in order to infringe." *Id*. Thus, a claimed compound in a

5 Every other claim of the '868 patent depends from either claim 1 or claim 9, and therefore the term "A compound" is included in every claim.

combination product is covered by the compound claims, not because the claims recite the combination (they do not), but because the combination contains the claimed compound. The Court should therefore construe the term "A compound" according to its ordinary meaning to cover the claimed compounds, whether or not other compounds, such as thienamycin-type compounds, are also present.

A. The Term "A compound" Should be Given its Plain and Ordinary Meaning.

The term "A compound" had a straightforward meaning to a person of ordinary skill in the art in the 1978-80 timeframe and the Court should construe it in accordance with that meaning. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc) ("[T]he words of a claim are generally given their ordinary and customary meaning.") (internal quotation marks omitted). The 1977 version of Hawley's Condensed Chemical Dictionary defines "compound" as "[a] substance composed of atoms or ions of two or more elements in chemical combination." (A1000-1004 at A1003-1004 (Gessner G. Hawley, *The Condensed Chemical Dictionar*y 223-24 (9th Ed., Van Nostrand Reinhold Co. 1977))). This definition is consistent with the claims of the '868 patent, which recite the chemical names or formulas of compounds and parts of compounds, using well understood terms to refer to atoms and ions of various elements joined by chemical bonds.

Ranbaxy has not proposed an alternative definition of "A compound" itself. Instead, Ranbaxy argues that the term should exclude the claimed compounds when they are used in combination with other compounds, specifically, thienamycin-type compounds, as in their proposed ANDA products.

B. The Term "A compound" Covers the Claimed Compounds When They are Used in Combination With any Other Compounds.

Contrary to Ranbaxy's argument, the intrinsic record establishes that the claims of the '868 patent were intended to cover the claimed compounds when they are used in combination with thienamycin-type compounds, even though such thienamycin-type compounds are not elements of the '868 patent claims. In fact, it is apparent from the specification that the primary purpose of the claimed compounds was precisely for use in combination with the unclaimed thienamycin-type compounds.

The abstract makes clear at the beginning of the patent that the "[n]ovel chemical compounds" of the patent "are useful ***in combination with antibacterial products.***" (A1-21 at A1 ('868 Patent Abstract)). The specification identifies the preferred use of the compounds as the use in combination with the unclaimed thienamycin-type antibacterial compounds. (A1-21 at A5-6 ('868 Patent, col. 8, ln. 41 - col. 9, ln. 45, "Methods of Using the Invention")). Moreover, the patent devotes three columns to describing thienamycin-type compounds and how to make them. (A1-21 at A4-5 ('868 Patent, col. 5, ln. 20 - col. 8, ln. 40)). Plainly, the '868 patent contemplates the use of the claimed compounds in combination with thienamycin-type compounds.

In patent law, anyone who "makes, uses, offers for sale or sells a patented invention" commits patent infringement. 35 U.S.C. 271(a). The Federal Circuit has repeatedly held that a patent covers the use of a claimed invention in combination with other unclaimed elements, even where the combination was the invention of another. *Atlas Powder Co. v. E.I. Du Pont de Nemours & Co.*, 750 F.2d 1569, 1580-81 (Fed. Cir. 1984); *Stiftung v. Renishaw PLC*, 945 F.2d 1173, 1178 (Fed. Cir. 1991) ("[A] pencil structurally infringing a patent claim would not become noninfringing when incorporated into a complex machine that limits or controls what

the pencil can write.") (citing *A.B. Dick Co. v. Burroughs Corp.*, 713 F.2d 700, 703 (Fed. Cir. 1983)).

The Federal Circuit's *Atlas Powder* case is illustrative of how 35 U.S.C. 271(a) provides for claim coverage and infringement in this situation. In that case, the Court considered the situation where "Atlas patents A + B + C and Du Pont then patents the improvement A + B + C + D." *Atlas Powder*, 750 F.2d at 1580-81. The use A + B + C in combination with the compound D was separately patentable and, therefore, was not part of Atlas' invention of A + B + C. Thus, Atlas could not draft claims to the use of A + B + C with D, because A + B + C + D was not Atlas' invention. Nonetheless, the Federal Circuit stated that "Du Pont is liable to Atlas for ***any*** manufacture, use, or sale of A + B + C + D because the latter directly infringes claims to A + B + C." *Id.*

Thus, under *Atlas Powder*, the word "compound" in the '868 patent claims would cover the claimed compounds whether or not used in combination with other unclaimed elements, such as thienamycin-type compounds. The claims cover this use, not because the combination was part of the invention of the '868 patent (it was not), but because the combination of (a) the claimed compound and (b) thienamycin-type compounds includes the claimed compound (just as the combination of A + B + C + D in *Atlas Powder* would infringe because it includes A + B + C).

C. The '868 Patent Specification Acknowledges That the Combination Dipeptidase Inhibitors With Thienamycin-Type Compounds was the Invention of Another.

In fact, the '868 patent inventors advised the Patent Office and the public that the combination of dipeptidase inhibitors with thienamycin-type compounds was the invention of another, but that the '868 patent inventors contemplated the use of their claimed compounds in

such a combination product. Immediately under the heading "Methods of Using the Invention," the '868 patent states,

> As mentioned above, the thienamycin-type compound is used in combination with the dipeptidase inhibitor. The combination product is not part of this invention, but is claimed in a copending application, Case 16174, U.S. Ser. No. 927,213, filed Jul. 24, 1978, now abandoned, and in Case 16174IA, U.S. Ser. No. 050,232, filed Jun. 22, 1979, now abandoned, and in Case 16174IB, filed concurrently herewith.

(A1-21 at A5 ('868 Patent, col. 8, lns. 43-51)). Thus, the '868 patentees acknowledged that the combination of product of thienamycin-type compounds with dipeptidase inhibitors was "not part of this invention," *i.e*. the invention of the '868 patent application. Rather, the combination product was claimed in the copending application of another Merck inventive entity, namely Kahan and Kropp.

Kahan and Kropp discovered that the dipeptidase enzyme metabolizes thienamycin and that, by inhibiting this enzyme, thienamycin could be successfully administered to humans. (A1072-1093 at A1076-1078 (U.S. Pat. No. 4,539,208 ("the '208 Patent"), col. 8, ln. 19 - col. 10, ln. 26)). Kahan and Kropp identified existing compounds that had some activity as an inhibitor. (A593-605 at A596 (U.S. Appln. Serial No. 06/748,300, Communication to the Examiner received June 25, 1985)). That discovery led Kahan and Kropp to their invention of the combination product of a thienamycin antibiotic and a dipeptidase enzyme inhibitor. (A1072-1093 at A1073 ('208 Patent, col. 1, lns. 14-37)).

However, Kahan and Kropp did not make the critical invention of an entire new class of compounds, including cilastatin. The '868 patent inventors--Graham, Rogers, and Kahan--made that discovery. Cilastatin and other novel compounds of the '868 patent were

more powerful as inhibitors of the dipeptidase enzyme than the existing compounds Kahan and Kropp looked at earlier.

Merck sought patent protection for both (a) the invention by Graham, Rogers, and Kahan of a new class of compounds, and (b) the invention by Kahan and Kropp of a combination product of thienamycin-type compounds and dipeptidase inhibitors. However, at the time, the patent law required that all persons listed on a patent as inventors must have contributed to the subject matter of every single claim in the patent. *See In re Berg*, 140 F.3d 1428, 1433-34 (Fed. Cir. 1998). Consequently, Merck sought claims for Graham, Rogers and Kahan's new class of compounds in one patent application (which led to the '868 patent), and Merck sought claims for Kahan and Kropp's combination product in a different patent application (which led to the now-expired U.S. Patent No. 4,539,208 and other patents). (*See* '868 Patent, col. 28, ln. 9 – col. 40, ln. 40; '208 patent, col. 38, ln. 4 – col. 40, ln. 52).

Accordingly, the paragraph quoted above from the '868 patent specification explains that the claims for the two inventions were included in two different sets of patent applications. All the same, the '868 patent specification advises that the use of the claimed compounds in combination with thienamycin-type compounds is a "Method[] of Using ***the Invention***" of the '868 patent. As noted above, the term "use" is a term of art in patent law that refers to an action that would infringe a patent. *See* 35 U.S.C. § 271(a). Here, by referring to "Methods of ***Using*** the Invention," the patentees made it clear that the use of the claimed compounds in combination with thienamycin-type compounds infringes the claims of the '868 patent.

Ranbaxy attempts to use the above quoted paragraph from the specification to support its position, contending that the specification disclaimed the combination by saying that

"the combination product is not part of this invention." According to Ranbaxy, a patent claim to a compound does not cover that compound when it is used in a combination that was not the invention of the patent. Ranbaxy is wrong. As discussed above with respect to *Atlas Powder*, a claim to a compound covers the claimed compounds, even when used in combination with unclaimed elements and even where the combination product is the invention of another. That rule also applies where the different inventive groups for the two inventions worked at the same company. *In re Kaplan*, 789 F.2d 1574, 1575, 1577-78 (Fed. Cir. 1986).

In *Kaplan*, one inventive entity (Kaplan only) invented and patented a process using a solvent, referred to here as "solvent A" for convenience. *Kaplan*, 789 F.2d at 1575. A second inventive entity (Kaplan and Walker) invented a process using solvent A in a mixture with other solvents, called the "solvent mixture A + B," for convenience. *Id.* The "Kaplan only" patent application described the use of the solvent mixture A + B because it was the best mode of practicing Kaplan's invention, even though A+B was the invention of Kaplan and Walker. *Id.* Of course, Kaplan could not obtain claims in his "Kaplan only" patent to the solvent mixture A + B because it was a different invention, invented by Kaplan and Walker, and it was not part of the "Kaplan only" invention. All the same, there was no dispute that Kaplan's claim to a process using solvent A covered a process of using the solvent mixture A + B. *Id.* at 1577-78.

Likewise, here, the term "A compound" in claims 1 and 9 of the '868 patent covers the claimed compounds alone or when they are used in combination with any other unclaimed compounds, including thienamycin-type compounds.

II. THE TERM "7-(L-2-AMINO-2-CARBOXYETHYLTHIO)-2-(2,2-DIMETHYLCYCLOPROPANECARBOXAMIDO)-2-HEPTENOIC ACID" IN CLAIM 19 INCLUDES THE FREE ACID, ESTER, AND CORRESPONDING SALT FORMS

The next claim construction issue relates to claim 19's use of the word "acid" in the term: "7-(L-2-amino-2-carboxyethylthio)-2-(2,2-dimethylcyclopropanecarboxamido)-2-heptenoic ***acid***." (A1-21 at A20 ('868 Patent, col. 40, lns. 21-23)). The parties dispute whether claim 19 uses the word "acid" in its broad generic sense to include free acid forms, ester forms, and salt forms, or whether it is limited to the free acid form.[6]

A. The '868 Patent Uses the Word "acid" in its Broad Sense

There is no dispute that the word "acid" can have different meanings depending on the context in which it is used. In particular, the word "acid" can be used in a broad generic sense, including free acid forms, as well as other forms, such as salt forms. *Merck & Co. v. Teva Pharms. USA, Inc.*, 347 F.3d 1367, 1371-72 (Fed. Cir. 2003) (construing the term acid "broadly" to include corresponding salt forms). Alternatively, the word "acid" can be used in a narrow sense to refer only to a free acid. *Pfizer Inc. v. Ranbaxy Labs. Ltd.*, 457 F.3d 1284, 1291 (Fed. Cir. 2006) (noting, however, that "acid" can be construed to include the corresponding salts, depending on the context in which it is used.).

The '868 patent specification shows the context in which the word "acid" is used in the patent. The specification consistently uses the word "acid" in its broad sense to refer to free acid forms, ester forms, and salt forms. In particular, with respect to the compound at issue in claim 19, the specification uses the word "acid" to include the salt form of that compound,

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6 Ranbaxy also proposes a construction relating to the R and S configurations based on the use of the chemical term "2,2-dimethylcyclopropane" in claim 19. Merck discusses that same issue with respect to the use of "2,2-dimethylcyclopropyl" in claims 2 and 9 in Section V.D below.

stating "***Sodium*** Z-7-(L-amino-2-Carboxethylthio)-2-(2,2-dimethylcyclopropane carboxamido)-2-heptenoic ***acid***." (A1-21 at A17 ('868 Patent, col. 34, lns. 11-13 (Example 19A))). Plainly, the compound referred to in the specification is a salt form, but the specification still refers to it as an acid.

The '868 patent also refers to other sodium salt forms as "acids." (A1-21 at A19 ('868 Patent, col. 37, lns. 59-62, "Z-2-(2,2-Dimethylcyclopropanecarboxamido)-7-sulfo-2-***heptenoic acid sodium salt***" and "Z-2-(2,2-Dimethylcyclopropanecarboxamido)-8-sulfo-2-***octenoic acid sodium salt***"))). Similarly, the patent also refers to ester forms of compounds as "acids." (A1-21 at A20 ('868 Patent, col. 3, lns. 44-48 ("2-dimethylaminoethyl ***ester*** of Z-2-(2,2-dimethylcyclopropanecarboxamido)-2-butenoic ***acid***"; 3-diethylaminopropyl ester of Z-2-(2,2-dimethylcyclopropanecarboxamido)-2-pentenoic acid))).

The '868 patent repeatedly uses the word "acid" to encompass the ester and salt forms of the acid. This usage confirms that one of ordinary skill in the art reading the '868 patent would readily understand that the word "acid" recited in claim 19 is not limited to the free acid form, but instead includes the salt and ester forms. Indeed, in *Merck*, the patent at issue referred to the "formulation of various biphosphonic acids for administration '***as the sodium salt***,' 'in the salt form,' 'in the form of Na salt,' and as '4-amino-1-hydroxybutan-1, 1-biphosphonic ***acid, sodium salt***.'" *Merck*, 347 F.3d at 1370. Likewise, here, in view of the '868 patent's usage of the word "acid" to encompass more than just the free acid form, Merck's construction should be adopted. *See Revlon Consumer Prods. Corp. v. L'Oreal S.A.*, 170 F.R.D. 391, 401 (D. Del. 1997) ("Nor will this Court accept a construction that is inconsistent with the patent's internal logic.") (citing *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 390

(1996) (indicating preference for a construction comporting with patent's internal "logic" and "coherence")).

B. Contemporaneous Patents Support Merck's Construction

Contemporaneous patents from before or about the time of the invention further support Merck's construction. Those patents show that persons of ordinary skill in the art at the time of the invention often used the word "acid" to refer not only to the free acid, but also to the ester and corresponding salt forms of that acid. For example, U.S. Patent No. 4,421,912 ("the '912 patent") to Takeda, filed in February 1981 and claiming priority through divisionals back to 1974, states the following in its specification:

> When the ***carboxylic acid*** compound [XIII] ***is employed in the form of free acid or salt***, a suitable condensing agent is used together. (A1005-1034 at A1009 ('912 Patent, col. 8, lns. 56-58)).
>
> The ***carboxylic acid*** compound [XIII] ***can be used*** in the acylation reaction ***as the free acid or as the corresponding salt*** with sodium, potassium, calcium, trimethylamine, pyridine or the like . . . . (A1005-1034 at A1009 ('912 Patent, col. 8, lns. 24-28)).

Similarly, U.S. Patent No. 4,414,196 ("the '196 patent") to Sakai Chemical, filed in November 1981 and claiming priority back to November 1980, states the following in its specification:

> The hydroxycarboxylic acids may be used in the form of a free acid, a water soluble salt or a water soluble ester. (A1035-1041 at A1038 ('196 Patent, col. 3, lns. 10-12)).
>
> The organic phosphoric acid may be used in the form of a free acid, a water soluble salt or a water soluble ester. (A1035-1041 at A1038 ('196 Patent, col. 3, ln. 68 - col. 4, ln. 2)).

Further, U.S. Patent No. 4,393,083 ("the '083 patent") to Kikkoman Corporation, filed in June 1981 and claiming priority back to July 1980, states the following in its specification:

> The term ***"cyclic-3',5'-adenylic acid"*** (hereinafter referred to briefly as cAMP), as used herein, ***includes the free acid and an alkali or alkaline earth metal salt thereof***, such as, for example, sodium, potassium or calcium salt. The ***suitable cAMP derivatives***

> ***include allyl esters*** such as N^6,$O^{2'}$ -dibutyl ester-cAMP and N^6 -butyl ester-cAMP. (A1051-1058 at A1053 ('083 Patent, col. 3, lns. 15-21)).

The '912, '196, and '083 patents demonstrate that persons skilled in the art often use the word "acid" not only to refer to a free acid, but also to its esters and corresponding salt forms.

III. THE TERM "PHARMACEUTICALLY ACCEPTABLE CATION" AND THE DEFINITION OF R^1 IN CLAIMS 1 AND 9

In this section, Merck discusses the parties' proposed definitions of "pharmaceutically acceptable cation" in claims 1 and 9. Merck also discusses the definition of group R^1 in claims 1 and 9, each of which includes the term "pharmaceutically acceptable cation."

A. "pharmaceutically acceptable cation"

Claims 1 and 9 recite a "pharmaceutically acceptable cation" as part of the definition of the Group R^1. (A1-21 at A19-20 ('868 Patent, col. 38, lns. 18-19; col. 39, lns. 31-32)). The parties' respective proposed construction for the term "pharmaceutically acceptable cation" is set forth below:

Merck:	"a cation acceptable for pharmaceutical use in connection with the claimed compounds."
Ranbaxy:	"Any cation useful in the salt form of the claimed pharmaceutical compound."

(Joint Claim Chart at 3). Merck's construction tracks the language of the claim and should be adopted.

In contrast to Merck's construction, Ranbaxy's construction impermissibly reads out an express limitation from the claim—namely, that the "cation" be "pharmaceutically acceptable." *See Texas Instruments Inc. v. U.S. Int'l Trade Comm'n*, 988 F.2d 1165, 1171 (Fed. Cir. 1993) ("[T]o construe the claims in the manner suggested by [the patentee] would read an

express limitation out of the claims. This, we will not do."). Indeed, the claim language does not permit any cation useful in the claimed compound, but only those that are "pharmaceutically acceptable." Ranbaxy's construction, which recites "***[a]ny cation*** useful in the salt form of the claimed pharmaceutical compound," plainly fails to account for that language. *See Exxon Chem. Patents, Inc. v. Lubrizol Corp.*, 64 F.3d 1553, 1557 (Fed. Cir. 1995) ("We must give meaning to all the words in [the patentee's] claims."). Indeed, under Ranbaxy's construction, even a cation that was ***not*** "pharmaceutically acceptable" could be used.

B. The Definitions of Group R^1 in Claims 1 and 9 do not Require Further Construction

Claims 1 and 9 define the group R^1, which includes the term "pharmaceutically acceptable cation" as well as other terms.

Claim 1: "R^1 is hydrogen or a pharmaceutically acceptable cation." (A1-21 at A19 ('868 Patent, col. 38, lns. 18-19)).

Claim 9: "R^1 is hydrogen, loweralkyl of 1-6 carbon atoms, dialkyaminoalkyl, or a pharmaceutically acceptable cation." (A1-21 at A20 ('868 Patent, col. 39, lns. 29-32)).

The only term that the parties dispute in the definitions of group R^1 are "pharmaceutically acceptable cation." whose construction is the subject of separate issue in the parties' Joint Claim Construction Chart. There is no remaining claim construction issue for the definition of group R^1 beyond the disputes over the meaning of these two terms. Certainly, the parties do not dispute the meaning of the word "hydrogen," nor do they dispute the definition of "loweralkyl of 1-6 carbon atoms." Accordingly, Merck submits that no construction of the overall definition of group R^1 in claim 1 is warranted or required.

Ranbaxy, however, proposes that the definitions of group R^1 in claims 1 and 9 be construed as follows:

Ranbaxy's rewritten version of claim 1:

> "R^1 defines two mutually exclusive subgenera: (1) a ***free acid*** form in which R^1 is hydrogen, and (2) ***salt*** forms in which R1 is a pharmaceutically acceptable cation." (Joint Claim Chart at 4).

Ranbaxy's rewritten version of claim 9:

> "R^1 defines three ***mutually exclusive subgenera***: (1) a ***free acid*** form in which R^1 is hydrogen, and (2) ***ester*** forms in which R^1 is loweralkyl of 1-6 carbon atoms, or dialkylaminoalkyl, and (3) ***salt*** forms in which R^1 is a pharmaceutically acceptable cation." (Joint Claim Chart at 14).

Ranbaxy's constructions add language found nowhere in the claims, such as "free acid form," "ester forms," and "salt forms." Indeed, R^1 in claim 1 is not recited as a "free acid" or a "salt," but rather, a "hydrogen" or a "pharmaceutically acceptable cation."

In addition, the claims do not define group R^1 in terms of "mutually exclusive subgenera" in describing group R^1. Ranbaxy thus proposes to add a technical issue relating to "mutually exclusive subgenera" that the claims do not even mention. Ranbaxy also never explained how construing the overall definition of group R^1, to include for example a requirement of "mutually exclusive subgenera," relates to any issue in the case.

Because all terms in the definitions of group R^1 in claims 1 and 9 are either not disputed or the subject of separate claim construction issues, Merck submits that the phrase requires no additional construction.

IV. THE MEANING OF VARIOUS COMPOSITE CHEMICAL GROUPS IN CLAIM 1 USING THE TERM "ALKYL," SUCH AS "TRIALKYLAMMONIUM."

Ranbaxy proposes that the Court make a claim construction ruling regarding certain composite chemical terms in claim 1 that incorporate the term "alkyl," such as

"trialkylammonium."[7] Ranbaxy does not proffer a definition for any of these terms, but rather proposes a construction for the use of the term alkyl in each of those terms: "[e]ach alkyl group in each substituent includes a linear, branched, or cyclic alkyl group without limitation as to number of carbon atoms." (Joint Claim Chart at 8). Ranbaxy's proposal should be rejected.

"Alkyl" should always be understood in the context of the composite chemical terms at issue here. These composite terms are conventional terms in organic chemistry that are well-understood by persons of ordinary skill to refer to known chemical groups. For example, a contemporaneous patent, U.S. Patent No. 3,657,298, which issued on April 17, 1972, confirms that similar composite chemical groups, such as "dialkylamino" and "alkoxy groups," are "conventional and generally widely known elements or groups of elements." (A1059-1071 at A1060 ('298 Patent, col. 3, lns. 32-33)). According to the '298 patent, "heretofore known organic chemistry" regarding these chemical groups "is widely known." (A1059-1071 at A1060 ('298 Patent, col. 3, lns. 21-27)).

Ranbaxy's contention that the alkyl groups in these composite chemical terms are "without limitation as to the number of carbon atoms" is inconsistent with the meaning of the composite terms as a whole to a person of ordinary skill in the art. To a person of ordinary skill, terms such as "trialkylammonium" call to mind a particular class of compounds. They do not refer to hypothetical compounds with alkyl groups so large they could never actually be made. Indeed, the '298 patent from 1972 noted that, with respect to certain chemical groups, "the nature of said groups ***as to the number of carbon atoms***" was "widely known." (A1059-1071 at A1060 ('298 Patent, col. 3, lns. 26-28)). Thus, the number of carbon atoms in each alkyl is not

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7 The other terms include "quaternary hydroxyalkyl-dialkylammonium," "phosphonylalkyl-amino," "hydroxyalkylamino," "alkylamidino," "N,N-dialkyguanidino," "alkylcarbonyloxy," "alkoxycarbonyl," and "N,N-dialkylcarbamoyl" in claim 1.

unlimited, and the appropriate number of carbon atoms should be determined based on the understanding of persons of ordinary skill in the art in the context of the composite chemical group as a whole.

In fact, Ranbaxy does not even define the term "alkyl" in its proposed construction. Even the ordinary meaning of "alkyl" considered alone is inconsistent with Ranbaxy's proposal that there are no limits on the number of carbon atoms in an alkyl. The definition of "alkyl" alone means "a paraffinic hydrocarbon group which may be derived from an alkane by dropping one hydrogen from the formula." (A1000-1004 at A1002 (Gessner G. Hawley, *The Condensed Chemical Dictionar*y 27 (9th Ed., Van Nostrand Reinhold Co. 1977))). This definition would not include an unlimited number of carbon atoms. Moreover, as pointed out above, the term "alkyl" used as part of a larger chemical group or moiety has the meaning understood by persons of ordinary skill in the art in the context of that larger chemical group or moiety, so the construction of alkyl does not appear necessary at all.

V. THE DEFINITION OF GROUPS "X" AND "Y" OF CLAIM 1, THE DEFINITION OF GROUP "R^2" IN CLAIM 22, THE STRUCTURAL FORMULA DEPICTED IN CLAIMS 1 AND 9, AND THE TERM "2,2-DIMETHYLCYCLOPROPYL" IN CLAIMS 2 AND 9

The parties' next claim construction dispute relates to (a) the definitions of groups "X" and "Y" in claim 1, (b) the definition of group R^2 in claim 22, (c) the structural formula depicted in claims 1 and 9, and (d) the term "2,2-dimethylcyclopropyl" in claims 2 and 9.

A. The Definition of Groups "X" and "Y" in Claim 1 do not Require Construction

Ranbaxy proposes that the Court construe the groups "X" and "Y" in claim 1. However, claim 1 itself defines the groups "X" and "Y" as follows:

> ***X is*** unsubstituted or substituted branched or linear alkyl of three to ten carbon atoms wherein a non-terminal methylene can be replaced by oxygen, sulfur or SO2, where said substituents are

> selected from the group consisting of halogen or cycloalkyl of three to six carbon atoms, with the proviso that, when said alkyl is substituted by said cycloalkyl, X is not more than ten total carbon atoms, with the further proviso that not more than six hydrogens of said alkyl can be substituted by said halogen, and with the further proviso that the carbon adjacent to the carbonyl cannot be tertiary;
>
> ***Y is*** cycloalkyl of three to six carbon atoms, unsubstituted or substituted with one or two substituents where said substituents are selected from the group consisting of halogen or alkyl of one to four carbon atoms, with the proviso that, when said cycloalkyl is substituted by said alkyl, Y is not more than ten total carbon atoms.

(A1-21 at A19 ('868 Patent, col. 38, lns. 22-41)). Because "X" and "Y" are expressly defined in the claim, using terms that the parties do not dispute, Merck submits that they require no additional construction. *See Fitness Quest Inc. v. Monti*, No. 5:06cv2691, 2007 WL 2359821, at *5 (N.D. Ohio Aug. 16, 2007) ("***A term, defined within the claim where it is found, does not otherwise require construction***.") (refusing to construe claim term that was defined in the claim itself) (citing *Phillips v. AWH Corp*., 415 F.3d 1303, 1314 (Fed. Cir. 2005)).

Ranbaxy does not suggest that any of the terms used in the definitions of "X" and "Y" above require any construction. Instead, Ranbaxy proposes its own constructions for those terms—constructions that are apparently motivated by its invalidity arguments. Indeed, Ranbaxy's constructions do not really attempt to construe or further define "X" and "Y," but rather, merely provide a list of embodiments that it contends "X" and "Y" ***"at least"*** cover. For example, for "X," Ranbaxy proposes that

> X includes at least:
>
> a branched or linear alkyl group of four carbons substituted with a cycloalkyl group of six carbons (i.e., a cyclohexyl group),
>
> a branched or linear alkyl group of five carbons substituted with a cycloalkyl group of five carbons (i.e., a cyclopentyl group),
>
> a branched or linear alkyl group of six carbons substituted with a cycloalkyl group of four carbons (i.e., a cyclobutyl group), and

> a branched or linear alkyl group of seven carbons substituted with a cycloalkyl group of three carbons (i.e., a cyclopropyl group);

(Joint Claim Chart at 4-5).

Ranbaxy's constructions add no clarity to the definitions of "X" and "Y" found in the claim. Instead, Ranbaxy seeks to re-write the otherwise clear claim language in a manner that is incomplete (using the term "at least") and does not really define the groups "X" and "Y" at all. Indeed, even if such a request were a proper part of claim construction, Ranbaxy never identified what issues it believes its proposed constructions are relevant to. For that reason too, Merck submits that no additional construction of "X" and "Y" is required. *See Vivid Techs., Inc. v. Am. Science & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (only terms that need to be construed are those "that are in controversy, and only to the extent necessary to resolve the controversy").

B. The Definition of Group "R^2" in Claim 22 Does not Require Construction

Ranbaxy proposes that the Court construe the group "R^2" in claim 22. However, claim 22 itself defines that group as follows:

> ***R^2 is*** cycloalkyl of three to six carbon atoms substituted by two alkyl substituents of one to three carbon atoms each, witho the proviso that R^2 cannot contain more than ten carbon atoms.

(A1-21 at A20 ('868 Patent, col. 40, lns. 28-32)). Like the groups "X" and "Y" in claim 1, the group "R^2" is expressly defined in the claim in which it appears. Ranbaxy has not identified any terms within the definition as needing construction.

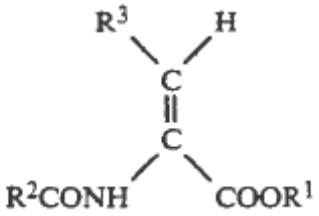
As with the groups "X" and "Y", Ranbaxy's construction of "R^2" does not attempt to construe or further define "R^2," but rather, merely provides a list of embodiments that Ranbaxy contends "R^2" ***"at least"*** covers. However, because "R^2" is defined in the claim in

which it appears and there is no dispute over any term in that definition, Merck submits that no additional construction of "R^2" is warranted or required

C. The Structural Formula Depicted in Claims 1 and 9 Does not Require Construction

Ranbaxy proposes that the Court construe the structural formula depicted in claims 1 and 9. The only disputes Ranbaxy has raised with respect to the structural formula, however, are identified elsewhere in the Joint Claim Construction Chart. Thus, the structural formula itself requires no further construction by the Court.

Claims 1 and 9 recite the following structural formula:



Ranbaxy does not dispute that the letters "C," "H," "O," and "N" in the structural formula refer to the elements carbon, hydrogen, oxygen, and nitrogen, respectively. Nor does Ranbaxy dispute that the single lines in the formula refer to single bonds and the double lines refer to double bonds. Ranbaxy also does not dispute that the formula depicts compounds in the Z stereoconfiguration and does not cover E stereoisomers.

As for, the groups R^1, R^2, and R^3, they are expressly defined in claims 1 and 9. To the extent the parties dispute any terms in the claims' definitions of those groups, they are addressed elsewhere in the Joint Claim Construction Chart, as discussed in other sections of this brief. Hence, the structural formula should not be construed separately here. *See Vivid Techs.*, 200 F.3d at 803 (only terms that need to be construed are those "that are in controversy, and only to the extent necessary to resolve the controversy").

D. The Term "2,2-Dimethylcyclopropyl" in Claims 2 and 9 Does not Require any Further Construction

Ranbaxy proposes that the Court construe the term "2,2-Dimethylcyclopropyl" in claims 2 and 9. Ranbaxy also proposes that the Court construe claim 19 with respect of its use with the same chemical group, referred to as "2,2-Dimethylcyclopropane" in that claim.

Merck contends that the Court does not need to construe this claim term. There is no dispute that a chemist reading this term would understand that the structure includes a chiral carbon, and that the chiral carbon could be in the S configuration ((S)-2-(2,2-dimethylcyclopropyl)) or in the R configuration ((R)-2-(2,2-dimethylcyclopropyl)). Thus, the term is a well known term in the art that needs no further construction.

Ranbaxy once again seeks to reword the claim, presumably to advance an invalidity argument. However, the claim term needs no construction, as it is a well known term in the art.

VI. THE TERM "SAID ONE TO FIFTEEN CARBON ALKYL" SHOULD BE CORRECTED TO READ "SAID TWO TO FIFTEEN CARBON ALKYL"

Claim 1 recites the term "said one to fifteen carbon alkyl." (A1-21 at A19 ('868 Patent, col. 38, ln. 60)). The term "one" in "said one to fifteen carbon alkyl" is a typographical error introduced as a result of an examiner's amendment at the end of the prosecution of the patent. Merck's construction would correct "said ***one*** to fifteen carbon alkyl" to read "said ***two*** to fifteen carbon alkyl." Ranbaxy cannot legitimately dispute that the word "one" is a typographical error. The real issue is whether the Court may correct that error.

The claim term "said one to fifteen carbon alkyl" appears in a proviso to the claim element for the group "R^3," defined as a two to fifteen carbon alkyl:

> R^3 is unsubstituted or substituted ***two to fifteen carbon alkyl*** wherein said substituent is halogen, and wherein a non-terminal methylene can be replaced by oxygen, sulfur or SO_2 and wherein

> the terminal carbon of said alkyl can be substituted by a moiety selected from the group consisting of [list of moieties], with the ***proviso*** that no more than six hydrogens of ***said one to fifteen carbon alkyl*** can be substituted by halogen . . . ."

(A1-21 at A19 ('868 Patent, col. 38, lns. 42-61)). The phrase "***said*** one to fifteen carbon alkyl" begins with the term of art "said," meaning that it refers to a claim element identified earlier in the claim. *See Intamin, Ltd. v. Magnetar Techs., Corp.*, 483 F.3d 1328, 1333 (Fed. Cir. 2007) ("The use of the word 'said' in a claim refers to an earlier use of the term in the claim.").

The claim term "***said*** one to fifteen carbon alkyl" could only refer to one prior claim term for the group R^3, namely, the ***two to fifteen carbon alkyl*** claim term. The phrase ***"said one to fifteen carbon alkyl"*** appears as a proviso in the R^3 claim element. The proviso limits the number of halogen substitutions on the alkyl of R^3. The only alkyl in R^3 with halogen substitutions is found in the phrase: "R^3 is unsubstituted or substituted ***two to fifteen carbon alkyl*** wherein said substituent is halogen,…" Plainly, the proviso limits the number of halogen substitutions in the "two to fifteen carbon alkyl." The word "one" in "said one to fifteen carbon alkyl" should have read "two."

Under well-established precedent, the Court may correct the error in the claim. In particular, courts may correct errors in a patent where "(1) the correction is not subject to reasonable debate based on consideration of the claim language and the specification and (2) the prosecution history does not suggest a different interpretation of the claims." *Novo Indus., L.P. v. Micro Molds Corp.*, 350 F.3d 1348, 1357 (Fed. Cir. 2003); *see also Hoffer v. Microsoft Corp.*, 405 F.3d 1326, 1331 (Fed. Cir. 2005) ("[w]hen a harmless error in a patent is not subject to reasonable debate, it can be corrected by the court . . . .").

Here, as to (1), the correction sought is not subject to reasonable debate. As an initial matter, it is apparent from the claim language itself that an error appears in the claim term

"***said*** one to fifteen carbon alkyl." Because the term "***said*** one to fifteen carbon alkyl" uses the word "said," it refers to an earlier claim term. However, the phrase "one to fifteen carbon alkyl" does not appear earlier in the claim, so the existence of the error is apparent. The obvious correction to that error is also apparent from the claim language itself, and not subject to reasonable debate. The "two to fifteen carbon alkyl" is the only claim term to which "***said*** one to fifteen carbon alkyl" could possibly refer, because the "two to fifteen carbon alkyl" is the one and only alkyl in group R^3 specified as substitutable with halogens. The correction is thus apparent, and not subject to reasonable debate, based just on consideration of the claim language.

As to (2), the prosecution history does not suggest a different interpretation of the term. In fact, it squarely supports Merck's construction. In particular, during prosecution, claim 1 was originally presented as claim 37. (A825-836 at A826-828 (U.S. Appln. Serial No. 07/839,725, Preliminary Amendment dated February 14, 1992)). As filed, the claim recited "one to fifteen carbon alkyl" and "***said*** one to fifteen carbon alkyl" as follows:

> R^3 is unsubstituted or substituted ***one to fifteen carbon alkyl*** wherein said substituent is halogen, and wherein a non-terminal methylene can be replaced by oxygen, sulfur or SO_2 and wherein the terminal carbon of said alkyl can be substituted by a moiety selected from the group consisting of [list of moieties], with the proviso that no more than six hydrogens of ***said one to fifteen carbon alkyl*** can be substituted by halogen . . . ."

(*Id*). Shortly thereafter, the applicant had an interview with the examiner. In the Examiner Interview Summary Record, the examiner states that ***"[t]he claims will be amended to exclude compounds wherein "R^3" is 1 carbon alkyl (i.e., "R^3" must be 2-15 carbons***)." (A841 (U.S. Appln. Serial No. 07/839,725, Examiner Interview Summary Record dated March 26, 1992)).

The examiner subsequently allowed various claims, including claim 37 (renumbered as claim 1 in the '868 patent). In an examiner's amendment, the examiner amended

claim 37 to change the word "one" to "***two"*** in the first recited instance of "one to fifteen carbon alkyl."[8] (A842-A845 at A844 (U.S. Appln. Serial No. 07/839,725, Notice of Allowability mailed March 30, 1992)). In so doing, however, the corresponding change was inadvertently not made to the second recited instance of "one to fifteen carbon alkyl"—an error that both the applicant and the examiner failed to notice. Thus, the prosecution history fully supports Merck's construction.

Merck's construction corrects "said one to fifteen carbon alkyl" to read "said ***two*** to fifteen carbon alkyl." Because the correction sought is both "not subject to reasonable debate" based on the claim language itself and "not contradicted by the prosecution history," Merck's construction should be adopted.[9]

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8 The examiner's amendment refers to the claim as "claim 39." The examiner plainly meant to refer to claim 37, however, as she had correctly stated in the previous sentence that "[c]laims 39 and 40 are cancelled…." (A842-A845 at A844 (U.S. Appln. Serial No. 07/839,725, Notice of Allowability mailed March 30, 1992)).

9 Ranbaxy has argued that claim 1 is indefinite, and consequently invalid, due to the typographical error. However, even if Merck's construction is not adopted, claim 1 would remain definite and not invalid. "R^3" is an "unsubstituted or substituted two to fifteen carbon alkyl" that can have halogen substitutions. Based on the language in the proviso, one of ordinary skill in the art reading the claim would readily understand the "two to fifteen carbon alkyl" of R^3 can have "no more than six hydrogens" substituted by halogen. Accordingly, claim 1 would not be indefinite in any event.

CONCLUSION

For the reasons stated above, Merck respectfully requests that the Court adopt Merck's proposed claim constructions.

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Dated: December 11, 2007
1332862

CERTIFICATE OF SERVICE

I hereby certify that on December 11, 2007, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to the following:

Frederick L. Cottrell , III, Esquire
RICHARDS, LAYTON & FINGER, P.A.

Kelly E. Farnan, Esquire
RICHARDS, LAYTON & FINGER, P.A.

Additionally, I hereby certify that true and correct copies of the foregoing were caused to be served on December 11, 2007 upon the following individuals in the manner indicated:

BY EMAIL (on 12/11/07)
AND HAND DELIVERY (on 12/12/07)

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